



U. S. Department of Justice
Drug Enforcement Administration
Office of Training
P.O. Box 1475
Quantico, Virginia 22134-1475

SEP 25 2003

Mr. Steve Mays
Manager, Regulatory Affairs
Amerisource Bergen
P.O. Box 959
Valley Forge, Pennsylvania 19482

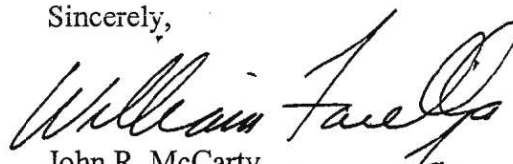
Dear Mr. Mays:

This letter is to confirm previous arrangements made by the Drug Enforcement Administration (DEA) Office of Training Class Coordinator Dorothy Coursey for a tour of the Bergen Brunswig facility in Richmond, Virginia, by our Diversion Investigator Trainees. I appreciate your cooperation, and I am certain that the visit to your distribution plant will be a valuable learning experience for our students.

The visit to Bergen Brunswig is scheduled for Friday, October 31, 2003. Approximately 30 employees, participating in the tour, will be arriving by bus at approximately 2 p.m. and we will depart your facility at approximately 4 p.m. for the return trip to Quantico, Virginia.

Again, thank you for your cooperation and support of the DEA Office of Training. Ms. Coursey will be in contact with you regarding further arrangements. In the meantime, if you should have any questions, please do not hesitate to contact her at (703) 632-5180.

Sincerely,


John R. McCarty
Special Agent in Charge

AM-WV-00782

Controlled Substance Regulatory Compliance

**Presented by AmerisourceBergen
Corporation in cooperation with the Drug
Enforcement Administration**

Steve Mays
Director, Regulatory Affairs
Security and Regulatory Affairs Dept.
AmerisourceBergen Corporation (ABC)
Valley Forge, PA

Statement of Goals

- The goal of this program is to provide the participants with an overview of the Pharmaceutical (Drug) Wholesale industry and the Wholesaler's compliance with 21 C.F.R. 1300 to the End. In addition, we will provide examples and methods of standard operating procedures of a full-line pharmaceutical wholesaler in an attempt to educate and thus enhance and build on the good working relationship between the Industry and DEA.

Objectives

- At the end of the presentation attendees should:
 - Understand the basic functions of a drug wholesaler with regard to distribution of controlled substances
 - Be familiar with the basic structure and departments of a drug wholesaler
 - Understand the Industry, basic operations and procedures and how they relate to 21 CFR 1300 to the end
 - Evaluate and understand the different types of reports and documents available during an audit

Wholesale Drug Distributors

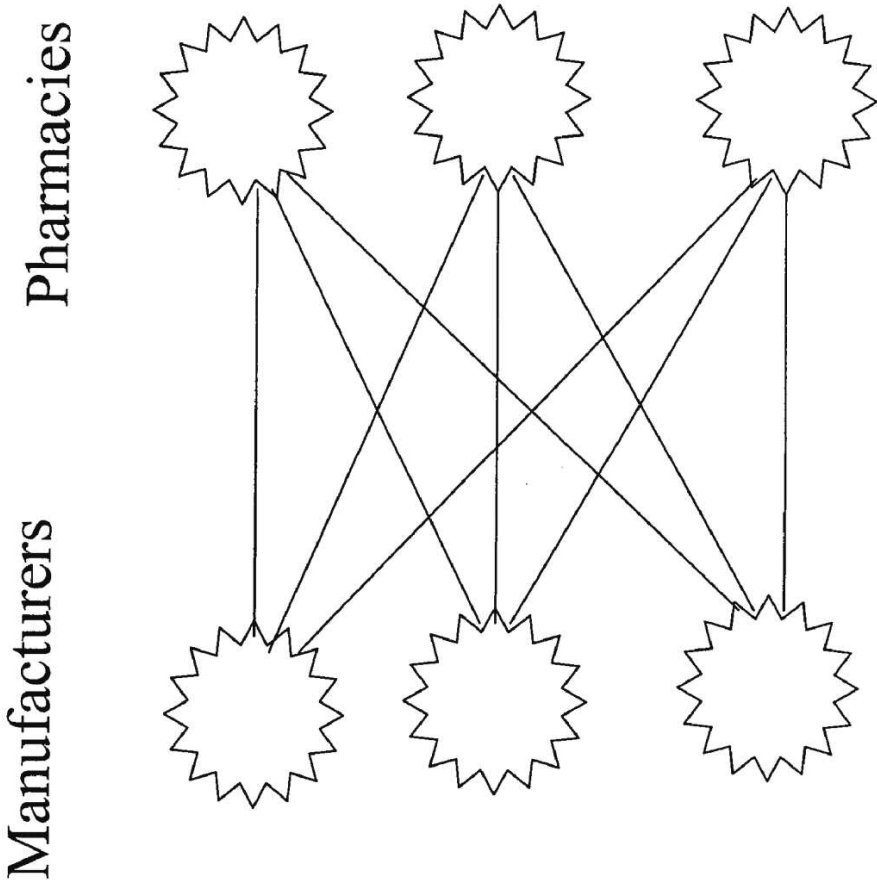
- There are over 3,000 different manufacturers of pharmaceuticals and health care products in the United States
 - ABC maintains approximately 140,000 SKUs (stock keeping units)
- There are over 130,000 pharmacy sites
 - Retail
 - Closed Door
 - Hospital

ROLE OF THE WHOLSALE DISTRIBUTOR

Without Distributors

Confusion and Complexity

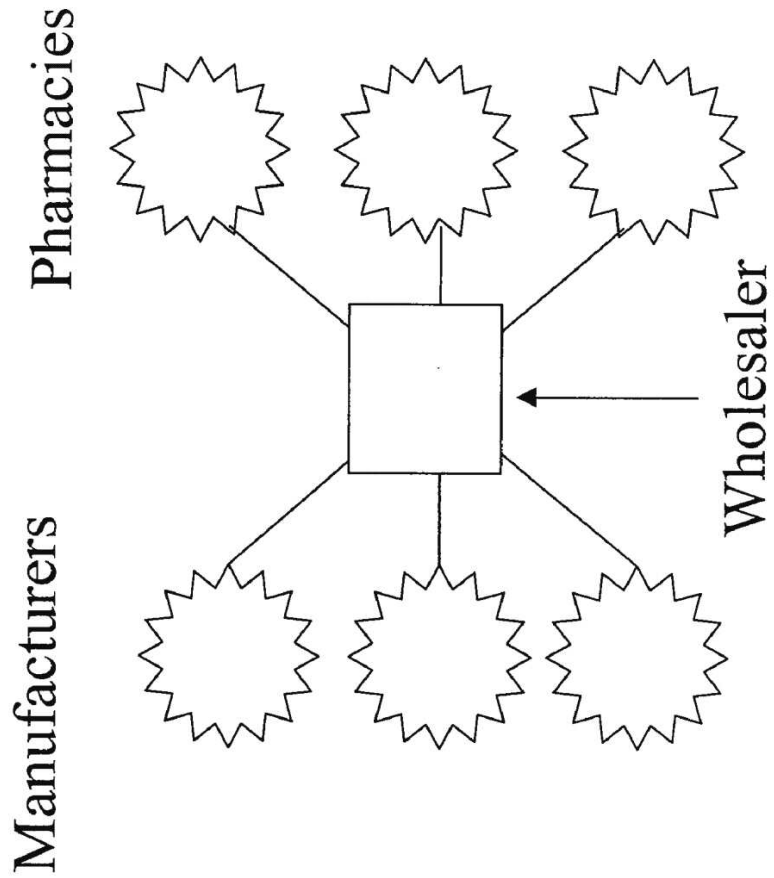
If all 130,000 pharmacy sites ordered product from all 3,000 manufacturers once a month the industry would generate 4.9 billion transactions each year



ROLE OF THE WHOLESALER DISTRIBUTOR

With Distributors
Control and Common
Sense

Utilizing the 80 drug
wholesalers that
number is cut to 124
million transactions
(97% reduction in
transactions)



Wholesale Drug Distributors

- There are approximately 80 wholesalers who operate approximately 230 distribution centers nationwide which generate approximately \$120 billion in sales annually
- The top 3 wholesalers account for approximately 90% of the market
- In the past decade the industry has cut operating expenses by over 30 percent
- Cutting operating expenses has not curved the steady decline in profit margins
- Average product mark-up is 1%
- Estimated net profits for Wholesale Drug Distributor is less than 1 percent (0.65%) of sales

Cost of Goods

- ABC's cost on Prozac (\$4,400)
 - At 1% mark-up, a distribution facility would need to sell \$440,000 dollars of product to recoup the loss of one bottle
- ABC's cost on a case of Claritin (\$34,000)
 - At 1% mark-up, a distribution facility would need to sell \$3.4 million of product to recoup the loss of one case

AmerisourceBergen Corporation

- AmerisourceBergen is the largest pharmaceutical services company in the United States dedicated solely to the pharmaceutical supply chain. It is the leading distributor of pharmaceutical products and services and is also a leader in the long term care pharmacy and workers' compensation fulfillment marketplaces.
 - ABC has been in business since 1889
 - ABC 2003 revenue - \$45 billion
 - Employs 14,000 people
 - ABC is ranked #24 on the Fortune 500 list
 - Operates 170 separate DEA registered locations
- ABC subsidiaries (ABSG, Pharmerica, AHP)

AmerisourceBergen Drug Company

- Operational Time Line (six days/week)
 - Receiving (6:00am - 2:00pm)- approx. \$125-190 million daily
 - Ordering (6:00am - 9:00pm) - approx. 100 - 1,000 night
 - Picking (12:00pm - 3:00 am) - approx. 10K - 70K Lines
 - Shipping (10:00pm - 6:00am)
 - Delivery (7:00 am - 4:00pm) - local and line haul

AmerisourceBergen Drug Company

- Drug Enforcement Administration Audits
 - Average approximately 12 audits each year
 - Each distribution center audited once every 3-5 years
- ABC Security and Regulatory Compliance Audits
 - Average approximately 30 audits each year
 - Each distribution center audited once every 6 - 18 months
- Other Regulatory Agencies Impacting Distribution
 - FDA (PDMA & New Food Handler Registration)
 - State Boards of Pharmacy/Departments of Health
 - Dept. of Transportation/FAA
 - OSHA
 - EPA (Rx Waste)
 - HIPAA (Patient Privacy)
 - Bureau of Wholesale Furniture

Code of Federal Regulations

- Interpretation
 - Between different facets of the Industry (Phcy, Dist, Mfg's)
 - Between Industry and DEA
 - Between DEA Field Offices and/or Washington

21 CFR 1301 - Security

- 1301.71 - provide effective controls to guard against theft and diversion (Internal/External)
 - Building Security
 - Physical Controls
 - Perception/Reality
 - Security Systems (alarm, access control, CCTV, etc.)
 - Segregated Areas (lobby, office, warehouse, parking)
 - Policy and Procedures
 - Employee entrance
 - Emergency exits
 - Visitor log and badges
 - No packages (purses, backpacks, etc.) in warehouse
 - No picking aprons outside warehouse

21 CFR 1301 - Security

- 1301.72 - Controlled Drug physical security
 - Vault & Cage
 - Physical
 - construction (concrete, modular, wire gauge)
 - security systems (different detection sensors)
 - Policy and Procedures
 - Access lists
 - Shipping and Receiving policies (DBL check, log)
 - Inventory control
 - Accountability is key

21 CFR 1301 - Security

- 1301.74 - Other security controls
 - Good faith license inquiry
 - MOST IMPORTANT FUNCTION
 - Wholesale distributors have an express duty to verify licensure and registration status of its customers
 - Customer File Set Up
 - on-site customer inspection
 - retain copy of each customer's registration
 - DEA information entered into computer system exactly as represented on actual registration certificate
 - only delivery to address in system

21 CFR 1301 - Security

- Customer File Maintenance
 - Customer DEA Review Report (NTIS)
 - reviewed monthly by each distribution center
 - also reviewed by corporate
 - Federal Register review daily
 - 30 and 60 day expiration reports printed at distribution centers
- License expiration notifications printed on invoices
- Computer system automatically "blocks" orders of expired registrations

21 CFR 1301 - Security

- 1301.74 - Other security controls
 - Suspicious order reporting system
 - Suspicious orders include orders of unusual size, deviating substantially from a normal pattern, and/or unusual frequency
 - Automated reporting system
 - Flexible reporting timeframes
 - Customer specific (retail, hospital, physician, etc.)

21 CFR 1301 - Security

- 1301.74 - Other security controls
 - Theft/loss reporting (DEA Form 106)
 - Common and contract carriers
 - Narcotic Treatment Center deliveries

21 CFR 1301 - Security

- **1301.90 & .93 - Employee Screening**
 - Prospective employees including temporary associates
- **All Associates**
 - Justifacts - ALL felony & misdemeanor convictions
- **"Compliance Critical" Personnel**
 - DEA - Drug related charges
 - Annual Justifacts

21 CFR 1304 – Records & Reports

- 1304.04 - Maintenance of records and inventories
 - 3 years plus current
 - Central Recordkeeping
 - not including executed DEA Form 222's or inventories
 - Records must be available within two business days of a written request
 - Schedule II records must be stored separately
 - Schedule III-V records stored separately or in a readily retrievable manner

21 CFR 1304 – Records & Reports

- 1304.11 - Inventory requirements
 - Complete and accurate record of all controlled substances on hand on the date the inventory is taken
 - ABC Policy and Procedures regarding shipping, receiving and returns
 - Inventories
 - Daily transaction activity counts (detect errors)
 - End of Month inventory of all Controlled Substances (saleable & unsaleable)
 - Year End ARCOS - Schedule II & III narcotics
 - Biennial - a complete inventory at least every two years

21 CFR 1304 – Records & Reports

- Area of confusion during audits/inspections
- 1304.22 - Records for distributors
 - Product name, description, quantity, name, addresses, DEA registration number, for all transactions (sales, receipt, credit, debit, etc.)
 - All of this information is available
- 1304.33 Reports to ARCOS
 - Filed monthly
 - All Schedule II and Schedule III narcotic products

HEMICAL EMERGENCY,
1-800-451-8346

AMERISOURCEBERGEN-PADUCAH
322 NORTH 5TH ST
PADUCAH, KY 42001
DEAN PLC032267 PH# 800-846-2472
S/L# W01157

AmerisourceBergen

INVOICE

RE-PRINT *
Ship Date 5/14/03 Inv/Div 3017160-17
STATS License POS025
BAPTIST HEALTHCARE SYST, INC-CIT ROUTE 382-010
CENTRAL BAPTIST HOSP DEPT PHCY
1740 NICHOLASVILLE ROAD
LEXINGTON, KY 40503
PH# 859-260-6659

Order# 8037318

Order Src RO EOL Conf. #
Stickers 25659

Item #	Quantity	Unit	Description	Lot #	Exp Date	Price	Net Price	Net Weight	Net Volume	Net Count	Net Total	Net Unit	Net Price	Net Weight	Net Volume	Net Count	Net Total	Net Unit
12	3017160	033162	4815															
2	CN	ATTIVAN 2MG/ML 10ML	BXI	10	VL	10019-102-10	4											
		** Refrigerate Upon Arrival																
0	EA	BREVITAL 800 500MG MDV				50ML VL 61570-095-01	4											
10	EA	Not Shipped * Expected Arrival Date : 07/21/03																
15	EA	BUTORPHANOL 2MG/ML	BDF	10	VL	55390-185-10	4											
16	EA	BUTORPHANOL 2MG/ML	APX	10	VL	60505-0660-0	4											
3	EA	HYDROCODONE/APAP 5/500	MLL	10	UD	0406-0357-62	3											
1	CN	KETAMINE 100MG/ML 5ML				0074-2051-09	3N											
20	CN	MIDAZOLAM HCL 1MG/ML 2ML	GBT	10	VL	10019-028-02	4											
10	CN	MIDAZOLAM 1MG/ML 5ML FTV				0074-2587-03	4											
61	EA	STADOL 2MG/ML				0015-5648-20	4											
39		** Not Shipped																

0.978.54 DTC Cost
Per Unit

Retail:
Freight:

Labels:

1-15TH/25TH 16-10TH/10TH



AmerisourceBergen

AMERISOURCEBERGEN-PADUCAH
322 NORTH 3RD ST
PADUCAH, KY 42001
DEA# FLO032327 PH# 800-946-2472

REPORT MERCH RETURN

BOOSSETT

CREDIT MEMO

ROUTE/STOP 383-10

* BAPTIST HLTHCARE SYST, IN-C11
CENTRAL BAPTIST HOSP DEPT PRCY
1740 NICHOLASVILLE ROAD
LEXINGTON, KY 40503

* BAPTIST HLTHCARE SYST, IN-C11
CENTRAL BAPTIST HOSP DEPT PRCY
1740 NICHOLASVILLE ROAD
LEXINGTON, KY 40503
4815 2740543

Ship Date	Ship To	Ship From	Reference Number	Invoice Number	Invoice Date	Invoice Amount	Page
6/05/03	5886154	33162		334	33162	AB3024243	1
Product Code	Qty	Unit	Description	Invoice	Invoice	Invoice	Invoice
4154704	2	EA	BUTORPHANOL 2MG/ML IN#3017160 PO# 4815	55390018510	4110	8220	0201
			BDF 10ML VL				

21 CFR 1305 - Order Forms

- 1305.03, .06, .09 & .11 - An order form (DEA Form 222) is required for each distribution of a Schedule II controlled substance
 - Alterations, incomplete
- 1305.07 - Power of Attorney
 - Authorized associates to sign DEA Form 222's
- Each DEA Form 222 is double-checked and matched against work order for accuracy and completeness
- 1305.15 - Cancellations
 - Purchaser cancellations
 - Supplier cancellations
- Automation will positively impact the Industry

21 CFR 1309 – Listed Chemicals

- Registration, Recordkeeping and Reporting
- 1309.21 - (Registration) Every person who distributes List I Chemicals shall obtain annually a registration specific to List I Chemicals
 - Exemptions
 - DEA Controlled Substance registration
 - "retail distributor"
- 1309.23 - Separate registration for separate locations
 - System automatically blocks customers without license

21 CFR 1310 – Listed Chemicals

- 1310.03 - (Recordkeeping) Required Records
 - Regulated transactions
- 1310.04 - Maintenance of Records
 - Regular business records are acceptable
 - Current plus 2 years
 - Central location record retention acceptable
 - "Readily Retrievable"

21 CFR 1310 – Listed Chemicals

- 1310.05 - (Reporting) Required Reports
 - Extraordinary quantity
 - Uncommon method of payment or delivery
 - Excessive loss or disappearance
- Reporting requirements for Chemicals are different than Controlled Substances
 - Oral notification upon discovery of loss
 - Written report must be filed within 15 days of oral notification
 - No DEA Form 106

Future Impact

- **Crime**
 - **Theft/Burglary**
 - **Counterfeit Product**
- **Controlled Substance Ordering System (CSOS)**
- **Listed Chemicals Storage Requirements**
- **Rescheduling of certain products**

Questions ?

- Industry
- AmerisourceBergen Corporation
- Registration
- Security
- Records and Reports
- Order Forms
- Listed Chemicals